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FDA's Failure to Inspect Clinical Trial Sites 'Puts Lives at Risk'

The FDA is conducting fewer inspections of clinical trial research sites, according to a Government Accountability Office report. Investigative journalist Maryanne Demasi, who in 2022 found the FDA's oversight in 2020 of COVID-19 vaccine clinical trials was "grossly inadequate," said the latest report shows "little has changed."

By Suzanne Burdick, Ph.D.

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FDA
U.S. Department of Health and Human Services
Food and Drug Administration

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The U.S. Food and Drug Administration (FDA) is conducting fewer inspections of clinical trial research sites than in past years, according to a recent report by the Government Accountability Office (GAO).

FDA officials attributed the decrease to the COVID-19 pandemic and a shortage of investigators, the federal watchdog said.

In preparing its report — which Congress commissioned — the GAO looked at FDA data and documents from fiscal years 2012 through 2023. It also interviewed an undisclosed number of FDA officials and 15 FDA investigators.

Investigative journalist Maryanne Demasi said she found the decrease in clinical research inspections "concerning."

Demasi — who in 2022 published an investigation in The BMJ that found the FDA's oversight in 2020 of COVID-19 vaccine clinical trials was "grossly inadequate" — told The Defender, "It appears that little has changed."

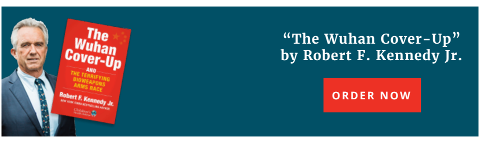
The FDA's lack of oversight is a big problem because the public relies on the quality and integrity of clinical trial data to ensure the safety of approved drugs, she said. "If the FDA drops the ball, as it appears to have done in the past few years, it puts people's lives at risk."

According to the GAO report, many FDA inspectors were frustrated, saying the agency often ignored their recommendations to take regulatory action when their inspections showed clinical research sites were out of compliance.

This is similar to what Demasi found during the COVID-19 clinical trials.

As she reported in The BMJ, a regional director overseeing Pfizer's COVID-19 mRNA vaccine complained to an FDA inspector about a range of problems including falsified data, unblinded patients and inadequately trained vaccinators who were slow to follow up on adverse events.

"I thought that the FDA was going to swoop in and take care of everything," the regional director told The BMJ. "What I was reporting was so important." But the FDA did not inspect the trial sites in question.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Clinical research entities not being held accountable

According to the GAO, six of the 15 investigators said they felt clinical research entities weren't being held accountable for the concerning observations made during inspections.

From fiscal years 2012 through 2020, the FDA classified only 3% of clinical research inspections as having serious deficiencies that would warrant regulatory actions.

This small figure is partly because the FDA downgraded more than half of the inspections completed in those years — meaning that although the inspectors initially classified the problems they found during their inspection as big enough to warrant official action, the FDA changed that to a less serious classification that didn't require FDA action.

An example of official action is the FDA sending a warning letter to the clinical research site for not following study protocols by improperly enrolling subjects that didn't meet eligibility requirements, or improperly administering doses of the study drug outside the required schedule, according to the GAO.

The FDA's downgrading of the inspectors' classifications frustrated the inspectors and affected their morale, the GAO said.

FDA inspectors take higher-paying jobs in drug industry

Relatively low pay also frustrated inspectors which, in turn, led to retention challenges. For example, two investigators who spoke with the GAO left the FDA for higher-paying industry jobs.

The FDA has increased the salary for new hires and offers up to $60,000 in student loan replacement, but FDA officials said compensation is still a challenge because the agency can't match the salaries offered by the drug industry.

"Given that its operating budget is around $6.2 billion and half of that is discretionary, the FDA should be doing more to recruit and retain staff to meet the demands of the agency and improving morale among workers," Demasi said.

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FDA prioritizes inspections tied to new drug approvals

Each year, the FDA initially determines the total number of inspections it plans to conduct based on available staffing resources and historical trends.

But if there aren't enough staff to complete all the planned inspections, priority is given to inspecting sites related to pending drug marketing applications to avoid delaying drug approval decisions.

That means inspections for ongoing clinical research may be delayed, the GAO said.

In other words, when the FDA doesn't have sufficient staffing to police all clinical research sites it thinks should be inspected, it prioritizes which sites to inspect to prevent delays for the companies paying user fees.

"In negotiating the user fees with the drug industry," the GAO report said, "FDA commits to meeting certain performance goals, such as reviewing marketing applications within a specified time frame."

These user fees, together with annual funding from Congress, pay for the FDA's work, according to the FDA's website about user fees.

Additionally, the rate of inspections hasn't kept up with the rate of drug applications.

The FDA conducted only 537 inspections in fiscal year 2022 — a 45% decline from its peak in fiscal year 2017 — even though the number of drug applications before the agency remained consistent, reported Government Executive.

"As a result of conducting fewer inspections, FDA may have less information to inform its review of marketing applications and surveillance of ongoing clinical research," the GAO said.

FDA continues remote inspections, despite investigators' concerns

Another issue inspectors told the GAO they were concerned about was the FDA's continued use of remote inspections to inform its drug approval decisions.

In response to the COVID-19 pandemic, the FDA in March 2020 stopped all in-person inspections, except those deemed mission critical, and began using remote regulatory assessments to help counteract the decrease in on-site inspections.

Despite resuming normal operations for domestic inspections in July 2021 and foreign inspections in March 2022, the FDA "is exploring the continued use of remote regulatory assessments in the future, including both when on-site inspections are not feasible and for more regular use for certain entities," the GAO said.

Most of the investigators interviewed by the GAO noted numerous challenges with remote assessments — such as issues with accessing requested electronic documents — and preferred conducting on-site inspections.

For instance, some investigators said assessing a site remotely gives pharmaceutical companies time to edit documents or create new

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'It's staggering that the FDA still hasn't got its act together'

Additionally, the GAO found that most of the FDA's inspections occurred at domestic locations, despite a 2022 GAO recommendation that the agency improve its foreign inspection program.

More than 50% of drug manufacturers supplying the U.S. market are located overseas, the GAO noted in its 2022 report.

"Also," Demasi said, "the [2024] GAO report indicates the FDA still doesn't have a comprehensive list of clinical research trials sites that are eligible for inspection, which was called out by the Office of Inspector General back in 2007."

"It's staggering that the FDA still hasn't got its act together," she added.

The GAO report recommended the FDA evaluate its recruitment and retention efforts for its investigators — such as increased pay, student loan repayment and other financial incentives — to figure out whether these efforts are working.

In response, the U.S. Department of Health and Human Services (HHS) — which oversees the FDA — said the FDA is committed to following the recommendation, the GAO said.

HHS also said the FDA will use the results of that evaluation "to ensure the agency is using the most appropriate tools" to maintain its bioresearch monitoring investigator workforce.

The FDA did not immediately respond to The Defender's request for comment.

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Suzanne Burdick, Ph.D.

Suzanne Burdick, Ph.D., is a reporter and researcher for The Defender based in Fairfield, Iowa.

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"Dr. McCullough: "It's a Complete Crime That Americans Were Denied Ivermectin""

"Countless numbers of lives were lost based on the irresponsible actions of the US FDA."

Dr. McCullough says, "Ivermectin is safer than Tylenol" and "has over 100 supportive studies" proving its effectiveness in the treatment of C19.
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Judge Forces CDC to Release Hidden COVID-19 Vaccine Injury Reports
"The CDC doesn't want you to see this."

The U.S. Centers for Disease Control and Prevention (CDC) has released **previously hidden reports of facial paralysis and other adverse events following COVID-19 vaccination.**

The 780,000 reports were received shortly after the COVID-19 vaccines were rolled out, and show people experienced a wide range of post-vaccination problems, **including heart inflammation, miscarriages, and seizures.**

"**Loss of consciousness and seizure immediately following injection.** Went to ER by ambulance," one person reported.

"Diagnosed with **Bells Palsy today due to left-sided facial numbness and paralysis**," another said.
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"THINKING"
"*Plus Bill Gates and the Gates Foundation, needs to be Deposed, Plus "all" Communications involving him and his Foundation with the "FDA". Subpoenaed"*

We need to know if his secret MOU with the FDA played 'any' Role in Suppressing Ivermectin, and Hydroxy, which could have SAVED Legions!
https://www.zerohedge.com/p...

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"FDA explicitly recognizes that doctors do have the authority to prescribe ivermectin to treat COVID,"
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Revisionist history.

Doctors were fired, had their licenses pulled for prescribing it.
Don't forget to read the comments...

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The FDA refusing to provide COVID-19 vaccine safety data!
U.S. officials are refusing to provide a U.S. senator with COVID-19 vaccine safety data.

Sen. Ron Johnson (R-Wis.) asked the U.S. Food and Drug Administration (FDA) for the results of analyses on data from the Vaccine Adverse Event Reporting System (VAERS) in January, after the U.S. Centers for Disease Control and Prevention (CDC) stated that none of the safety signals it identified for the COVID-19 vaccines were "unexpected."

The two agencies have run different types of analyses on the system's reports, which are primarily made by health care professionals.

The CDC ran Proportional Reporting Ratio analyses, which involve comparing the number of reported adverse events to the number of adverse events reported after vaccination with other vaccines.

The first time the agency ran analyses using the method for the COVID-19 vaccines, in 2022, hundreds of signals were triggered, files obtained by The Epoch Times show.
https://www.theepochtimes.c...

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"*FDA Director Dr. Peter Marks Says **They Received an 'Avalanche' of Adverse Event Reports After the COVID-19 Vaccines Were Released*"** Feb 15, 2024 before Congress.

"Florida's Surgeon General **told the FDA that COVID vaccines aren't safe.** The FDA calls that misinformation."
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"CHD? "New FDA Informed Consent Rules?"
"What You Should Know About FDA Final Informed Consent Guidance"

On August 15, 2023, FDA published a final guidance entitled, "Informed Consent, Guidance for IRBs (Institutional Review Boards), Clinical Investigators, and Sponsors." This final guidance supersedes the September 1998 guidance entitled "A Guide to Informed Consent" and replaces the July 2014 draft guidance "Informed Consent Information Sheet."
https://www.wcgclinical.com...

"NUREMBURG VIOLATIONS CONTINUE ON YOU IN THE US !!!!!:New FDA Rule Allows for Medical Research Without Informed Consent"
In an effort to encourage the discovery of more treatment and diagnostic options in the medical field, the **U.S. Food and Drug Administration (FDA) has finalized a rule allowing certain clinical trials to operate without obtaining informed consent from participants.**

The hitch? The study cannot pose more than minimal risk to humans and must include appropriate safeguards to protect the rights, safety, and welfare of those involved.

The rule was issued in late December 2023 and **went into effect on Jan. 22, 2024.**

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